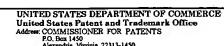


United States Patent and Trademark Office



APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,809	02/08/2002	Michael J. Rochon	11009-0019	9593
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Clark & Brody Suite 600 1750 K Street, NW			EXAMINER	
			PAK, JOHN D	
Washington, DC 20006		•	ART UNIT	PAPER NUMBER
			1616	6
		•	DATE MAILED: 07/09/2003	٠).

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10/067,809 Applicant(s)

Examiner

Art Unit John Pak

1616

Rochon



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on *Mar 31, 2003* 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. **Disposition of Claims** 4) X Claim(s) 1, 2, 4-10, 12-40, and 42-54 is/are pending in the application. 4a) Of the above, claim(s) ______ is/are withdrawn from consideratio is/are allowed. 5) ☐ Claim(s) 6) 💢 Claim(s) <u>1, 2, 4-10, 12-40, and 42-54</u> is/are rejected. 7) Claim(s) _____ is/are objected to. are subject to restriction and/or election requirement 8) L Claims **Application Papers** 9) \square The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are a accepted or b objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a approved b disapproved by the Examine If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some* c) ☐ None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 5) Notice of Informal Patent Application (PTO-152) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s).

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Claims 1-2, 4-10, 12-40, 42-54 are pending in this application. At the outset, applicant is advised that election of species requirement regarding the phosphorus-based acid is hereby withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in-
- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 4-7, 9, 12-15, 46, 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Micciche et al. (US 6,043,209).

Micciche et al. explicitly disclose a cleaning composition that contains, inter alia, the following ingredients (see Example 1 on column 4):

- 3 wt% hydrogen peroxide;
- 0.6 wt% sodium lauryl (dodecyl) sulfate;
- 0.12 wt% DEQUEST 2010 (1-hydroxyethylidene-1,1-diphosphonic acid);
- 0.23 wt% sodium lauroyl sarcosinate + 0.07 wt% lauramine oxide + 0.25 wt% C11-15 pareth 7 surfactants.
- 92.87 wt% water.

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See from column 3, line 10 to column 4, line 37 for broader ranges and pH ranges of 5.5-7.0.

The claims are thereby anticipated, because the prior art composition contains the same ingredients as the claimed composition. Applicant's "consisting essentially of" language is noted, but according to the MPEP (2111.03), such partially closed language is still open to other additives that "do not materially affect the basic and novel characteristics" of the claimed invention. If applicant contends that the additional ingredients in the prior art composition are excluded by the "consisting essentially of" language, the burden is on applicant to show that the addition of such ingredients would materially change the characteristics of applicant's invention.

In the instant case, applicant's invention is an aqueous disinfecting or sanitizing composition of a certain pH range. The prior art composition is patentably indistinguishable in that it is also an aqueous cleaning composition with a pH range that is within applicant's claimed range. There is nothing about the additives in the prior art composition that would materially affect (i) the disinfecting or sanitizing properties of the composition, or (ii) any other basic and novel characteristics of the claimed invention.

The features of claims 46 and 47 are noted, but "up to 20 wt./wt. %" language is already readable on the prior art composition, and "can be diluted" language does not require any actual further dilution.

For these reasons, the claims are anticipated.

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Claims 1-2, 4-7, 9-10, 12-15, 18, 20-23, 26-27, 32-33, 35-37, 39, 42-44, 46-49, 51, 54 are rejected under 35 U.S.C.102(b) as being anticipated by Greene et al. (US 4,518,585)¹.

Greene et al. explicitly disclose an aqueous disinfecting and sterilizing composition that contains the following ingredients (column 2, lines 3-18 & 40-41; column 4, lines 22-25):

- 0.5-50 wt% hydrogen peroxide, 0.5-10 wt% preferred;
- 0.1-30 wt% surfactant that is compatible with hydrogen peroxide;
- 0.1-3 wt% organic or inorganic acid;
- 0-1 wt% organic triazole corrosion inhibitor;
- 0.01-1 wt% aqueous alcoholic mixture of tertiary amine and fatty acid alkanolamide, which serves as both a surfactant and a corrosion inhibitor;

water;

pH below 5, preferably below 3.

The surfactant can be an anionic such as sodium lauryl sulfate, disodium 4-dodcecylated oxydibenzenesulfonate (column 3, lines 15-23). It is noted for the record that the nomenclature "oxydibenzenesulfonate" is equivalent to sulfonated diphenyl oxide. The acid can be any organic or inorganic acid, e.g. phosphoric acid. The corrosion inhibitor is present when treating a metal

¹ Parent application to this application has issued as U.S. Patent No. 6,346,279. The claims there are directed to aqueous compositions that contain as required ingredients 0.05-8 wt/wt% hydrogen peroxide, 0.05-8 wt/wt% phosphoric acid or phosphoric acid + phosphonates, 0.02-5 wt/wt% C8-16 alkyl aryl sulfonic acids/salts. Different independent claims have additional ingredients. This ground of rejection and any other ground of rejection in this Office Action and any subsequent Office Action are not directed to such patented subject matter. The patented subject matter in the 6,346,279 patent is outside the scope of any ground of rejection herein.

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surface, and not required when treating non-metallic surfaces (column 4, lines 4-11). The alcohol includes lower alkanols such as isopropyl alcohol at 1-10 wt% of said alcoholic mixture (column 4, lines 24-28). The tertiary amine and fatty acid alkanolamide would provide emulsifier functionality.

The claims are thereby anticipated, because the prior art composition contains the same ingredients as the claimed composition. pH 1-3 is readily envisaged by disclosures of pH below 3 and within-range pH of other examples, e.g. pH 1.8 in Example 1 on column 4. Applicant's "consisting essentially of" language is noted, but according to the MPEP (2111.03), such partially closed language is still open to other additives that "do not materially affect the basic and novel characteristics" of the claimed invention. If applicant contends that the additional ingredients in the prior art composition are excluded by the "consisting essentially of" language, the burden is on applicant to show that the addition of such ingredients would materially change the characteristics of applicant's invention.

In the instant case, applicant's invention is an aqueous disinfecting or sanitizing composition of a certain pH range. The prior art composition is patentably indistinguishable in that it is also an aqueous disinfecting and sanitizing composition with a pH range that is within applicant's claimed range. There is nothing about the additives in the prior art composition that would materially affect (i) the disinfecting or sanitizing properties of the composition, or (ii) any other basic and novel characteristics of the claimed invention.

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Dilution features of claims 46 and similar claims are noted, but "up to 20 wt./wt. %" language is already readable on the prior art composition, and "can be diluted" language does not require any actual further dilution. For these reasons, the claims are anticipated.

Claims 1, 4-6, 9, 12-15, 22, 24, 28, 46, 47, 49, 50 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Silvaggi et al. (WO 98/18894).

Silvaggi et al. explicitly disclose a cleaning and disinfecting composition that contains, inter alia, the following ingredients (see from p. 27, line 22 to p. 29, line 9):

5 wt% hydrogen peroxide;

3 wt% sodium alkyl sulfate;

0.1 wt% chelant;

0.1 wt% salicylic acid;

1 wt% isopropyl alcohol;

1 wt% ethoxylated tetraethylenepentamine;

water;

pH 5.

Hydrogen peroxide may be present in a broader range of 0.01-20 wt% by weight (p. 8, lines 5-7). Sodium alkyl sulfate is C8-22 alkyl sulfates (p. 14, lines 25-26). The chelant is a DEQUEST phosphonate (p. 29, lines 5-6; see also the paragraph bridging pages 21 and 22). Alkali metal

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ethane 1-hydroxy diphosphonates² are explicitly disclosed (p. 21, line 27). At pH 5, the phosphonates would be protonated to provide the phosphonic acid form. The ethoxylated tetraethylenepentamine would have emulsifier properties. It is noted that component (iv) in claim 9 is optional: "up to 3 wt./wt. %" reads on 0%.

The claims are thereby anticipated, because the prior art composition contains the same ingredients as the claimed composition. Applicant's "consisting essentially of" language is noted, but according to the MPEP (2111.03), such partially closed language is still open to other additives that "do not materially affect the basic and novel characteristics" of the claimed invention. If applicant contends that the additional ingredients in the prior art composition are excluded by the "consisting essentially of" language, the burden is on applicant to show that the addition of such ingredients would materially change the characteristics of applicant's invention.

In the instant case, applicant's invention is an aqueous disinfecting or sanitizing composition of a certain pH range. The prior art composition is patentably indistinguishable in that it is also an aqueous cleaning and disinfecting composition with a pH range that is within applicant's claimed range. There is nothing about the additives in the prior art composition that would materially affect (i) the disinfecting or sanitizing properties of the composition, or (ii) any other basic and novel characteristics of the claimed invention.

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² DEQUEST 2010 is alternatively known as 1-hydroxyethylidene-1,1-diphosphonic acid or ethane 1-hydroxy diphosphonic acid.

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The features of claims 46, 47, 49, 50 and 52 are noted, but "up to 20 wt./wt. %" language is already readable on the prior art composition, and "can be diluted" language does not require any actual further dilution.

The claims are thereby anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvaggi et al. (WO 98/18894)³.

Teachings of Silvaggi et al. have been discussed above, and the discussion there is incorporated herein by reference. Additionally, Silvaggi et al. teach that the C8-22 alkyl sulfates is interchangeable with C8-22 alkyl benzene sulfonates (p. 14, lines 22-27).

The difference between the claimed invention and the cited reference is that the reference does not expressly disclose dodecyl benzene sulfonic acid/salt in combination with hydrogen peroxide, phosphorus-based acid, and water (+emulsifier/hydrotrope in claim 16).

³ This ground of rejection and any other ground of rejection in this Office Action and any subsequent Office Action are not directed to the patented subject matter in U.S. Patent No. 6,346,279. This ground of rejection is directed solely to subject matter that is outside the metes and bounds of the claimed subject matter in said patent.

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However, one having ordinary skill in the art would have been motivated to substitute dodecylbenzene sulfonate for C8-22 alkyl sulfate, because Silvaggi et al. teach the specific interchangeability of the anionic surfactants alkyl sulfates and alkyl benezene sulfonates. Dodecyl benzene sulfonate is clearly suggested from C8-22 alkyl benzene sulfonates. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited reference.

Claims 1-2, 4-10, 12-40 and 42-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scoville, Jr. et al. (US 5,900,256, hereinafter, Scoville), Kennedy, Jr. (US 4,637,899, hereinafter, Kennedy) and Block.

At the outset, it is noted that certain of the presently claimed subject matter was already allowed during the prosecution of the parent application, now issued as U.S. Patent No. 6,346,279. Present ground of rejection is not applicable to the already patented subject matter. Present ground of rejection is directed solely to subject matter that is not encompassed by the subject matter of the patented claims in U.S. Patent No. 6,346,279.

Scoville teaches a cleaning and disinfection composition that contains:

0.5-50 wt% hydrogen peroxide;

0.001-10 wt% at least one organic or inorganic acid (e.g. acetic acid); corrosion inhibitor system + alkylene glycols (0.1-3.0 wt% range);

diluent.

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See column 3, lines 16-29, 45-53, and column 4, lines 52-61. It is noted that alkylene glycols would deliver "emulsifier" or "hydrotrope" functionality. pH is preferably below 3 (column 5, lines 11-15). Diluents include water, stabilizers, surfactants, and chelating agents (column 5, lines 9-11 & 16-18). Up to 30 wt% anionic surfactants such as sodium lauryl sulfate, sodium dodecylbenzenesulfonate or disodium 4-dodecylated oxydibenzenesulfonate (i.e. an alkylated sulfonated diphenyl oxide disodium salt) are disclosed (column 5, lines 32-33 & 49-56). Stability and compatibility with hydrogen peroxide and acidic condition are taught for such anionic surfactants (column 5, lines 32-37). Chelating agent, 1-hydroxyethylidene-1,1-diphosphonic acid (DEQUEST), is disclosed for enhancing biological activity (column 6, lines 7-12). Low amounts such as 0.7 and 3.0 wt% are disclosed (column 8, Compositions I and II). Phosphoric acid is suggested (column 6, lines 30-31).

Kennedy discloses a corrosion inhibitor composition that contains alcohols such as alkanols/glycols/polyols, and surfactants such as alkyl sulfonated diphenyl oxides (column 3, lines 18-22 & 38-46).

Block is cited to establish that hydrogen peroxide, acids and surfactants are known to possess individual disinfecting properties (pp. 167-180 and 256-271).

The difference between the claimed invention and Scoville is that Scoville does not explicitly disclose a specific composition that contains all of the claimed components in a single exemplified composition. However, as shown above, Scoville suggests all of the claimed components (with the exception of alkylated sulfonated diphenyl oxide, which is discussed

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below). Motivation to add each optional ingredient is provided: alkylene glycol for solubility, sodium lauryl sulfate or sodium dodecylbenzenesulfonate for surface active activity with compatibility in acidic-H₂O₂ environment, chelating agent such as 1-hydroxyethylidene-1,1-diphosphonic acid for improved biological activity.

As mentioned above, Scoville does not explicitly disclose alkylated sulfonated diphenyl oxides, e.g. C6 alkylated sulfonated diphenyl oxide disodium salt. However, Scoville teaches that such alkylated diphenyl oxide salts are suitable as anionic surfactants. Additionally, Scoville teaches that an effective corrosion inhibiting system is not limited to those specifically mentioned in his disclosure, and may incorporate one or more inhibitors (column 4, lines 41-48). Kennedy provides the nexus in that a corrosion inhibiting system that is useful for inhibiting acid-induced corrosion of metals (column 4, lines 24-28) contains 0-20 v% or 2-7 v% alkyl sulfonated diphenyl oxides and alkanols/glycols/polyols. One having ordinary skill in the art would have been motivated to utilize such a corrosion inhibiting system in Scoville's composition because Scoville's composition is an acid-containing cleaning composition that can corrode metals. Addition of Kennedy's corrosion inhibitor would advantageously protect metallic surfaces from Scoville's acid-containing composition. Specific selection of a C6 disodium salt from the teaching of "alkyl sulfonated diphenyl oxides" is held to be within the ordinary level of skill in this art, which would have led the ordinary skilled artisan to expect a mid-range alkyl such as C6 to be suitable, as well as disodium salts to be suitable salt forming moieties for the sulfonate anionic moieties.

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Block provides further motivation to combine hydrogen peroxide, acids, and surfactants, as claimed, because Block discloses the well known facts that all such ingredients have individual disinfecting activity, hydrogen peroxide is more effective at acidic pHs (p. 169, right column, first seven lines), and anionic surfactants are effective sanitizers at acidic pHs (p. 257, left column, last full paragraph; pp. 258-260; see Table 14-2 for dodecyl benzene sulfonic acid, dodecyl diphenyloxidedisulfonic acid, and other sulfonated anionics).

Applicant's "consisting essentially of" language is noted, but according to the MPEP (2111.03), such partially closed language is still open to other additives that "do not materially affect the basic and novel characteristics" of the claimed invention. If applicant contends that the additional ingredients in the prior art composition are excluded by the "consisting essentially of" language, the burden is on applicant to show that the addition of such ingredients would materially change the characteristics of applicant's invention. It is the Examiner's position that there is nothing about Scoville's composition that would detract it from functioning as an aqueous disinfecting and sanitizing composition, as claimed by applicant. Therefore, the additional ingredients in Scoville, vis-a-vis the various independently claimed embodiments by applicant, are not excluded by applicant's "consisting essentially of" language.

Applicant's arguments relative hereto, filed in Paper No. 7 (3/31/03) have been given due consideration, but they were deemed unpersuasive.

Applicant argues that it would not be obvious that using the inventive anionic surfactants would result in an unexpected boost in the disinfection ability of the base composition.

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Applicant ignores the state of the art. At the time Scoville taught up to 30 wt% of anionic surfactants such as sodium lauryl sulfate and sodium dodecylbenzenesulfonate, it was textbook knowledge that such anionics had individual disinfecting properties of their own (Block). The motivation and suggestion to use such anionic surfactants would have come from the advantage of obtaining dual functionalities: surface active activity and biocidal activity.

Applicant refers to the Ramirez affidavit for evidence of nonobvious evidence. Applicant is reminded that the claims are far broader than the evidence proffered by Ramirez. Evidence of nonobviousness, if any, must be commensurate in scope with that of the claimed subject matter.

In re Kulling, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); In re Lindner, 173 USPQ 356, 358 (CCPA 1972).

During the examination of the parent application, it was determined that the specific combination of alkyl aryl sulfonic acid/salt + phosphoric acid + hydrogen peroxide provided the necessary activity. Such subject matter was allowed – see the claims of the parent application, issued as US 6,346,279. Present ground of rejection is directed to subject matter that is outside the metes and bounds of the patented claimed subject matter. The evidence in Ramirez does not support the nonobviousness of subject matter that is outside the metes and bounds of the patented subject matter.

Table A in the Ramirez affidavit is similar to the Table A that was submitted in the affidavit by Ramirez in the parent application. The data in Table A is relevant to the already

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patented subject matter. This ground of rejection does not apply to the already patented subject matter.

Table B in the Ramirez affidavit does not actually establish anything nonobvious. A composition containing hydrogen peroxide and anionic surfactant is expected to be microbicidal. Nothing comparative is shown vis-a-vis the prior art. Similarly, Tables C and D establish only that which would have been expected. Composition ingredients such as the acidic phosphoric acid, hydrogen peroxide, and anionic surfactants are expected to be microbicidal. Table E is noted, but such results seem to indicate that virucidal activity is specific to very particular and empirical selection of several components. Clearly, Table E is not commensurate in scope with that of the entire claimed subject matter, i.e. all nine independently claimed sets of inventions. Presently, there appears to be no single claim that is limited to the particular choice, concentration and proportion of components in Formulations E3 to E5.

For these reasons, applicant's evidence falls short of being probative for the entire claimed subject matter in this application. Therefore, the claimed invention, as a whole, would have been <u>prima facie</u> obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited references.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 4 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JOHN PAK RIMARY EXAMINER GROUP 1600